

Practitioner's Docket No. MPI93-006CP1DV1ACN1DV1M

REMARKS

Claims 27 and 44-47 have been amended and claims 30, 32, and 34-41 have been canceled. Claims 48-58 have been added. Accordingly, claims 27-28, and 44-58 will be pending upon entry of the instant amendment. Support for these amendments can be found throughout the specification and claims as originally filed. Specifically, support may be found, for example, at page 12, lines 24-25; and at page 13, lines 20-24 of the specification as filed. No new matter has been added.

Priority

The Examiner objected to the priority, stating that "reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet," including "the relationship (i.e. continuation, divisional, or continuation-in-part)" and, "the current status of all nonprovisional parent applications." Applicants have addressed the Examiner's concern by amending the specification to insert as the first sentence a reference to the prior applications, their relationships, and status, as described in the Transmittal Letter filed 8/19/03.

Restriction

Applicants appreciate acknowledgment of Applicant's arguments resulting in the merger of Groups I and III and Groups II and IV. Applicants also appreciate acknowledgment of the election of merged Groups II and IV.

The Rejection of Claims 27-28, 34-41, and 44-45 Under 35 USC §112, First Paragraph, Should Be Withdrawn

The Examiner rejected claims 27-28, 34-41, and 44-45 under 35 USC §112, first paragraph, as failing to comply with the written description requirement. The Examiner argued that "the claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner states that "the instant claims read on a genus of isolated polypeptide sequences encoding any C140 receptor polypeptide," and "the two C140 sequences disclosed by applicants as well as the disclosed agonists and antagonists...are not a representative number of species sufficient to provide a description of the claimed genus." Cancellation of claims 34-41 obviates the rejection with respect to those claims. Applicants traverse the rejection and

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argue that the claimed subject matter is sufficiently described in the specification as filed. For example, Applicants have provided sequences of both murine and human C140 receptor from both genomic and cDNA sequences. Applicants have provided an alignment of murine and human C140 receptor polypeptides in Figure 3, showing high homology and conserved regions. Applicants disclose structural features of C140 receptors, (e.g. transmembrane domains, signal peptides, proteolytic cleavage sites, and activation peptides) in Figures 1, 2, 10, and 11, related Examples 1, 2, 4, and 5 and other structural information on pages 9-13 of the specification. Therefore, Applicants have provided multiple examples of the genus of C140 receptor polypeptides and structural features characteristic of the genus. Applicants submit that one of ordinary skill in the art, after successful hybridization of the encoding polynucleotide, could use this information to predict whether the encoded polypeptide sequence is a C140 receptor polypeptide. However, in an effort to expedite prosecution, Applicants have canceled claims 34-41, and amended claims 27 (and claim 28 dependent thereon) and 44 (and claim 45 dependent thereon) to recite an isolated polypeptide "wherein the polypeptide has cross-reactive antigenicity to at least 15 amino acids of the amino acid sequence of SEQ ID NO: 4 or SEQ ID NO:63." The inherent antigenicity of the disclosed polypeptides and fragments thereof provides relevant identifying characteristics in the form of structural and physical characteristics to show possession of the claimed genus. Applicants submit that this limitation, as described in the specification and understood in the art, and the teachings of the amino acid sequences in SEQ ID NO: 4 and SEQ ID NO:63, and the nucleotide sequences of SEQ ID NO: 3 and SEQ ID NO:62, referred to in the claims certainly render the specification sufficiently descriptive of the subject matter of the rejected claims (polypeptides of at least 15 amino acids encoded by nucleic acids which hybridize stringently to the nucleotide sequence of SEQ ID NOs:3 or 62, wherein the polypeptide has cross-reactive antigenicity to at least 15 amino acids of the amino acid sequence of SEQ ID NO: 4 or SEQ ID NO:63) in such a way as to convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants believe that the rejection of claims 28 and 45 has also been addressed by correction of the defect in the base claim. Therefore, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 27-28, 36, 37, 39-41, and 44-45 under 35 USC §112, first paragraph.

Obviousness Type Double Patenting

The Examiner rejected claims 27 and 36-40 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 5,763,575 "because both sets of claims recite agonists and antagonists of C140 receptor activity". Applicants have canceled claims 34-41, and amended claim 27 to recite polypeptides "having a consecutive sequence of at least 15 amino acids." Applicants submit that the claims as amended are not obvious in view of U.S. Patent No.

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5,763,575. Accordingly, the peptides of U.S. Patent No. 5,763,575 do not fall within the scope of the claims of the instant application as amended. Applicants respectfully request reconsideration and withdrawal of the rejection of claim 27 and 36-40 under the obviousness-type double patenting doctrine.

The Rejection of Claim 27 Under 35 USC §102(a) and §102(e) Should Be Withdrawn

The Examiner rejected claim 27 under 35 USC §102(a) and (e) as being anticipated by Polita et al. (U.S. Patent No. 5,143,903 issued September 1, 1993). Specifically, the Examiner argued that "no size limit is recited for the C140 polypeptide and hence the claim reads on any C140 sequence (e.g. two or three amino acids) which can be encoded by the recited nucleic acid molecules," and that Polita et al teach peptide compounds such as the tripeptide Pro-Leu-Tyr, "which is a C140 polypeptide" and "Polita therefore teaches the claimed invention."

Applicants traverse the rejection and respectfully submit that the claimed invention of the instant application and that claimed in Polita et al. are in fact very different. In an effort to expedite prosecution, Applicants have amended claim 27 to recite polypeptides "having a consecutive sequence of at least 15 amino acids". Thus, Applicants submit that Polita et al. do not teach each and every element of the pending claims as amended. In addition, Applicants therefore submit that the two inventions are distinct and that the tripeptides taught by Polita et al. do not fall within the scope of the claims as amended. Applicants respectfully request reconsideration and withdrawal of the rejection of claim 27 under 35 USC §102(a) and (e).

Miscellaneous

The Examiner stated that the Information Disclosure Statement (IDS) filed 8/19/03 was not of record in the file. For the Examiner's convenience, Applicants submit herewith a copy of the IDS filed, including one reference and forms PTO/SB/08A and PTO/SB/08B, and a copy of the stamped return postcard bearing the USPTO date and barcode. Applicants respectfully request review of the IDS for the next Office communication.

The Examiner objected to claims 30, 32, 46, and 47 as being allowable except for their dependence on a rejected base claim. Applicants have amended claim 46 to be in independent form, have amended claim 47 and have added new claims with similar scope as canceled claims 30, 32, 34, and 35 to be dependent on claim 46. Applicants respectfully request withdrawal of the objection.

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CONCLUSIONS

Applicants submit that in view of the foregoing remarks and arguments, this application is now in condition for allowance. No new matter has been added.

This paper is being filed timely as Applicants believe no extension of time is required. In the event any additional extensions of time are necessary, the undersigned hereby authorizes the requisite fees to be charged to Deposit Account No. 501668.

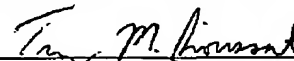
Entry of the remarks made herein is respectfully requested.

June 30, 2005

Respectfully submitted,

MILLENNIUM PHARMACEUTICALS, INC.

By



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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

COPY

In re application of:	Sundelin, Johan, et al		
Application No.:		Group No.:	
Filed:	Herewith	Examiner:	
For:	RECOMBINANT C140 RECEPTOR ITS AGONISTS AND ANTAGONISTS, AND NUCLEIC ACIDS ENCODING THE RECEPTOR		

Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

List of Sections Forming Part of This Information Disclosure Statement

The following sections are being submitted for this Information Disclosure Statement:

1. ☒ Preliminary Statements
2. ☒ Forms PTO/SB/08A and PTO/SB08B (substitute for Form PTO-1449) (2 pages)
3. ☒ Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted

CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) and 1.10*

I hereby certify that, on the date shown below, this correspondence is being:

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- ☒ deposited with the United States Postal Service in an envelope addressed to Mail Stop Patent Application, Commissioner for Patents, Washington, D.C. 20231.
37 C.F.R. SECTION 1.8(a)

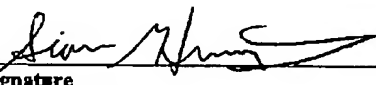
37 C.F.R. SECTION 1.10*

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Date: August 19, 2003


Signature
Sean Hunziker
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Preliminary Statements

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. section 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

**Identification of Prior Application in Which Listed Information Was Already Cited
and for Which No Copies Are Submitted or Need Be Submitted**

Copies of the listed documents were previously cited or submitted in parent Application No. 08/474,414, filed June 7, 1995, of which the instant application is a divisional (references A1, C1, C2, C3, C7, C9 and C10), and in related Application Nos. 08/472,840 (filed June 7, 1995, now U.S. Patent No. 5,763,575) (references B1 and B2) and 08/486,673 (filed June 7, 1995, now U.S. Patent No. 6,297,026) (references C4, C5, C6 and C8). Therefore, in accordance with 37 C.F.R. § 1.97 and 37 C.F.R. § 1.98(d), no copies of the documents are being submitted herewith. The exception to the foregoing is listed PCT Publication No. WO 89/01942 (reference B3), which was cited in a counterpart European Patent Office Application and is submitted herewith.

Respectfully submitted,

August 19, 2003

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	
		Filing Date	Herewith
		First Named Inventor	Sundelin, Johan, et al.
		Group Art Unit	
		Examiner Name	
Sheet 1 of 1	Attorney Docket Number	MPI93-006CP1DV1ACN1DV1M	

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and-or country where published.	T ²
	C1	Horuk, "Molecular properties of the chemokine receptor family," <i>TIPS</i> 151(5):159-165 (1994)	
	C2	Kaufman, "Vectors used for expression in mammalian cells," <i>Methods in Enzymology</i> , 185:487-511 (1990)	
	C3	Masu <i>et al.</i> , "cDNA cloning of bovine substance-k receptor through oocyte expression system," <i>Nature</i> , 329:836-838 (1987)	
	C4	Nystedt <i>et al.</i> , "Molecular cloning and functional expression of the gene encoding the human proteinase-activated receptor 2," <i>Eur J Biochem</i> , 232(1):84-89 (1995)	
	C5	Nystedt <i>et al.</i> , "The mouse proteinase-activated receptor-2 cDNA and gene. Molecular cloning and functional expression," <i>J Biol Chem</i> , 270(11):5950-5955 (1995)	
	C6	Nystedt <i>et al.</i> , "Molecular cloning of a potential proteinase activated receptor," <i>Proc Natl Acad Sci USA</i> , 91(20):9208-9212 (1994)	
	C7	Patel <i>et al.</i> , "The somatostatin receptor family," <i>Life Sci</i> , 57(13):1249-1265 (1995)	
	C8	Rudinger, "Characteristics of the amino acids as components of a peptide hormone sequence," <i>Peptide Hormones</i> , J.A. Parsons, ed., pp. 1-7, University Park Press, 1976	
	C9	Scarborough <i>et al.</i> , "Tethered ligand agonist peptides," <i>J Biol Chem</i> , 267(19):13146-13149 (1982)	
	C10	Vu <i>et al.</i> , "Molecular cloning of a functional thrombin receptor reveals a novel proteolytic mechanism of receptor activation," <i>Cell</i> , 64:1057-1068 (1991)	

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Unique citation design number. ²Applicant is to place a check mark here if English language Translation is attached.

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特許協力条約に基づいて公開された国際出願

(51) 国際特許分類 ⁴ C07K 15/06, 15/04, 3/20 A61K 39/00, 39/395, C12N 5/00 C12N 15/00, C12P 21/00 G01N 33/53, 33/577	A1	(11) 国際公開番号 WO 99/01947 (43) 国際公開日 1999年3月9日 (09.03.89)
(21) 国際出願番号 POT/JP88/00833 (22) 国際出願日 1988年8月22日 (22. 08. 88) (31) 優先権主張番号 特願昭 62-207403 特願昭 63-205690 (32) 優先日 1987年8月22日 (22. 08. 87) 1988年8月20日 (20. 08. 88) (33) 優先権主張国 JP (71) 出願人 (米国外を除くすべての指定国について) 三井東圧化学株式会社 (MITSUI TOATSU CHEMICALS, INCORPORATED) (JP/JP) 〒100 東京都千代田区新大塚三丁目2番5号 Tokyo, (JP) (72) 発明者 および (75) 発明者/出願人 (米国外についてのみ) 村松 善 (MURAMATSU, Takashi) (JP/JP) 村松 孝子 (MURAMATSU, Hisako) (JP/JP) 〒891-01 鹿児島県鹿児島市桜ヶ丘三丁目26番9号 Kagoshima, (JP) 井上 浩 (INOUE, Hiroshi) (JP/JP) 〒890 鹿児島県鹿児島市日之出町22-22 Kagoshima, (JP) 渡辺 昭 (AWAYA, Akira) (JP/JP) 〒244 神奈川県横浜市戸塚区矢部町1541番地 Kanagawa, (JP) 福井英雄 (FUKUI, Hideo) (JP/JP) 〒297 千葉県茂原市東部台三丁目9番9号 Ohiba, (JP)	橋本幸秀 (HASHIMOTO, Yoshihide) (JP/JP) 〒297 千葉県茂原市東部2141番地 Ohiba, (JP) (74) 代理人 弁護士 若林 忠 (WAKABAYASHI, Tadaashi) 〒107 東京都港区赤坂1丁目9番20号 第16興和ビル8階 Tokyo, (JP) (81) 指定国 AT (欧州特許), BB (欧州特許), CH (欧州特許), DE (欧州特許), FR (欧州特許), GB (欧州特許), IT (欧州特許), LU (欧州特許), NL (欧州特許), SE (欧州特許), US. 添付公開書類 国際調査報告書	
(54) Title: PROTEIN DERIVED FROM LIVING BODY (54) 発明の名称 生体由来のタンパク質 (57) Abstract <p>A protein specifically found in living bodies between fertilization and one week after birth, such as an embryonic brain of a mouse, and having a molecular weight of about 68,000 and an isoelectric point of 5.4 to 5.6 has been isolated by affinity chromatography using lectin as affinity ligand. A polyclonal antibody and a monoclonal antibody for the protein have also been prepared. The monoclonal antibody has been yielded by a hybridoma which can yield the monoclonal antibody. Further, separation of the protein from an extract of a living body using these antibodies have also been conducted. In the staining tests of cancer tissues of various cancer patients using these antibodies according to the vector staining methods A, B, C etc., these antibodies have been found to be useful as effective ingredients for cancer-diagnosing agents.</p>		

COPY

Attorney Docket No.: MPI93-006CP1DV1ACN1DV1M

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HEREON ACKNOWLEDGES THE FILING OF:

Description of Paper* and No.: New Application Transmittal (5 pages - in duplicate); 58 pages of Specification (including 49 pages of description, 8 pages of claims, and 1 page of abstract); 16 sheets of Drawings (Figures 1A-13); Paper copy of Sequence Listing (34 pages); Submission of "Sequence Listing" (4 pages); Two copies of an executed Declaration and Power of Attorney of prior U.S. Application Serial No. 08/390,301 (5 pages each); Information Disclosure Statement (2 pages); Forms PTO/SB/08A and PTO/SB/08B (2 pages); Preliminary Amendment (9 pages); Copy of Reference WO89/01947; and this return postcard.

Name of Applicant: Johan Sundelin, et al.

Serial No.:

Title: RECOMBINANT C140 RECEPTOR ITS AGONISTS AND ANTAGONISTS, AND NUCLEIC ACIDS ENCODING THE RECEPTOR

Attorney/Agent: Jean M. Silveri

Date: August 19, 2003

*with Certificate of Express Mailing No.: EL992152619US

Attorney Docket No.: MPI93-006CP1DV1ACN1DV1M

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Description of Paper* and No.: New Application Transmittal (5 pages - in duplicate); 58 pages of Specification (including 49 pages of description, 8 pages of claims, and 1 page of abstract); 16 sheets of Drawings (Figures 1A-13); Paper copy of Sequence Listing (34 pages); Submission of "Sequence Listing" (4 pages); Two copies of an executed Declaration and Power of Attorney of prior U.S. Application Serial No. 08/390,301 (5 pages each); Information Disclosure Statement (2 pages); Forms PTO/SB/08A and PTO/SB/08B (2 pages); Preliminary Amendment (9 pages); Copy of Reference WO89/01947; and this return postcard.

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08/19/03